

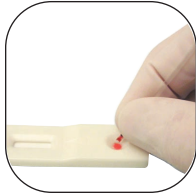
TEST INSTRUCTIONS



1. Remove the test device from the foil pouch, and place it on a flat, dry surface.



2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end.



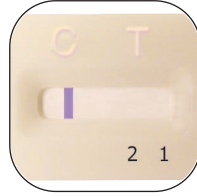
3. Touch the end of the micro-capillary tube to the sample pad and pinch the tube once again to release the sample. Make sure that you do not use more than 5ul of sample. If using whole blood, allow sample to absorb for 1-2 minutes before adding the HIV-3 diluent.



4. Slowly add 5 drops of HIV-3 sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window. **NOTE: full absorption of each drop is necessary to allow the sample to flow through the special filter in the sample well.**



5. Start the timer.



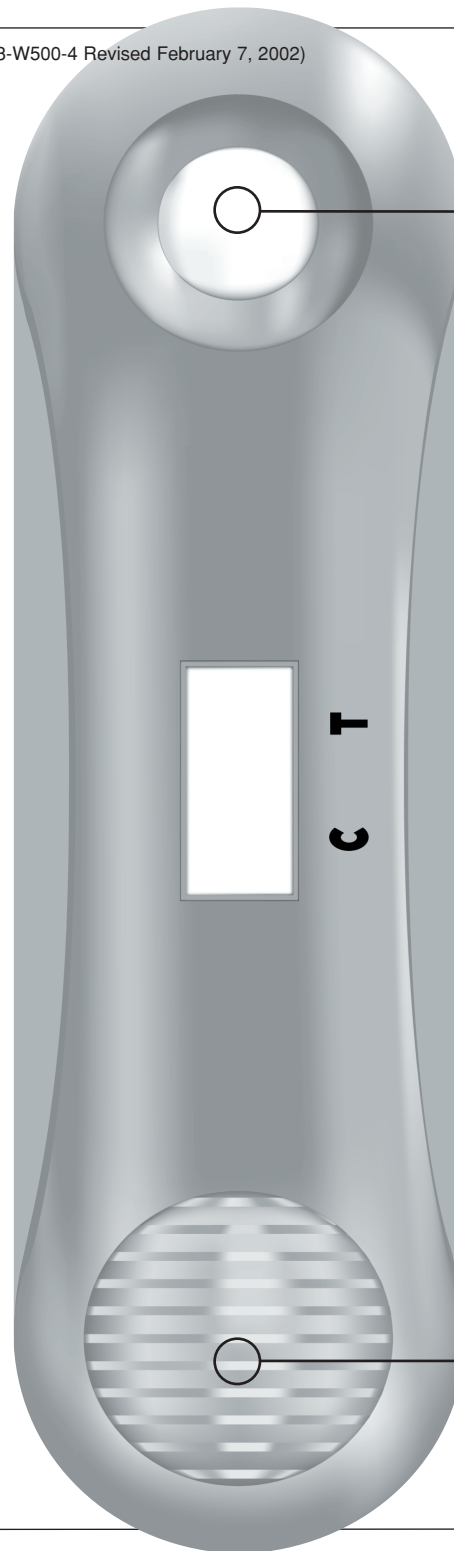
6. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.

7. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

Caution: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

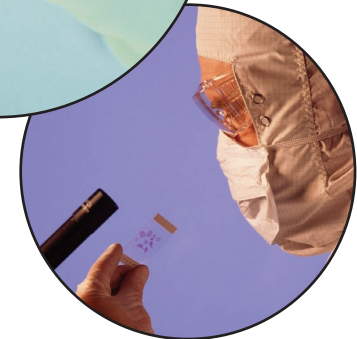
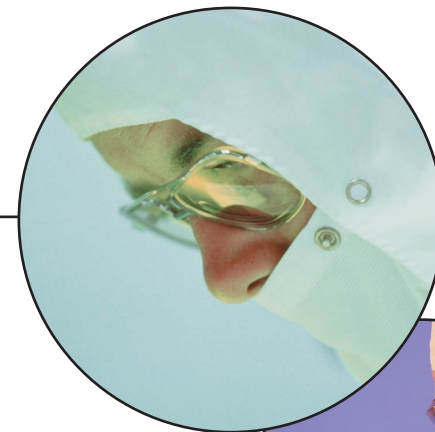
INTERPRETATION OF THE TEST

Positive	Negative	Invalid



*Making a difference
in the lives of millions*

**JN-QC™ HIV-TriLine
Rapid Single Use Test Device**



EXPLANATION OF THE TEST

HIV-1 has been isolated from patients with AIDS and AIDS related complex, and from healthy persons with high potential risk of developing AIDS (1). Patients with HIV-2 are found primarily in parts of West Africa (2). HIV-1 and HIV-2 are similar in their morphology, cell tropism, host interaction and generic structure. Serological studies have determined that HIV-1 and HIV-2 have multiple common epitopes in core antigens but much less so in the envelope antigens.

The JN-QC™ HIV-TriLine test cassette has the numbers 1 and 2 as well as the letters T and C as “Test Line” and “Control Line” areas respectively on the surface of the case. The “Control Line” is used for procedural control. The Control Line should always appear if the test procedure is performed properly and the test reagents of the Control Line are working. A purple “Test Line” next to the number 1 and 2 will be visible in the Result Window antibodies against HIV-1 pr HIV-2 are present in sufficient concentrations. If antibodies against HIV-1 and/or HIV-2 are not present, or are present at very low levels in the sample, then no color appears in the “Test Line”.

The JN-QC™ HIV TriLine test is a solid phase immunochromatographic assay for the qualitative detection of antibodies against HIV-1 and HIV-2. This test is intended for professional use as an aid for the diagnosis of HIV-1 and/or HIV-2 infections.

MATERIALS PROVIDED

- 1-JN-QC™ HIV-TriLine test device
- 1-Instruction sheet
- 1-Bottle of HIV-TriLine diluent
- 1-Disposable 5ul micro-capillary pipette

MATERIALS REQUIRED BUT NOT PROVIDED

- 1-Sample Collection Kit
- 1-Timer

PRECAUTIONS

The JN-QC™ HIV-TriLine test devices should be stored at room temperature. The test device is sensitive to humidity and to heat. Perform the test immediately after removing the test device from the foil pouch. **Do not use test beyond the expiration date.**

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested immediately or stored at 2-8 degrees C.

PLASMA/SERUM SPECIMEN COLLECTION:

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2-8 degrees C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use.

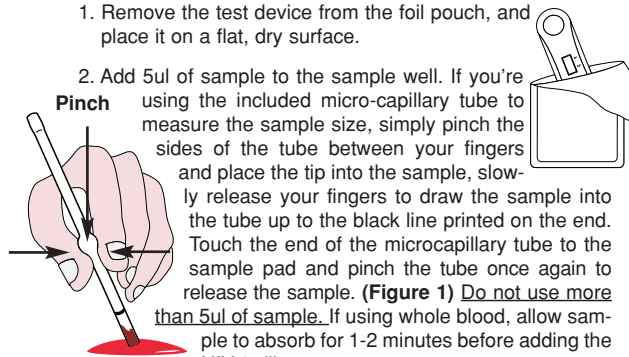
3. Specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

WARNINGS

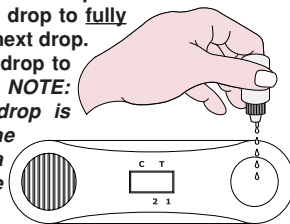
1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

TEST PROCEDURE

1. Remove the test device from the foil pouch, and place it on a flat, dry surface.
2. Add 5ul of sample to the sample well. If you're using the included micro-capillary tube to measure the sample size, simply pinch the sides of the tube between your fingers and place the tip into the sample, slowly release your fingers to draw the sample into the tube up to the black line printed on the end. Touch the end of the microcapillary tube to the sample pad and pinch the tube once again to release the sample. **(Figure 1) Do not use more than 5ul of sample.** If using whole blood, allow sample to absorb for 1-2 minutes before adding the HIV-3 diluent.



3. **Slowly add 5 drops of HIV-3 sample diluent to the sample well allowing each drop to fully absorb before adding the next drop. If required, add one more drop to fully clear the test window. NOTE: full absorption of each drop is necessary to allow the sample to flow through a special filter in the sample well. Start the timer.**

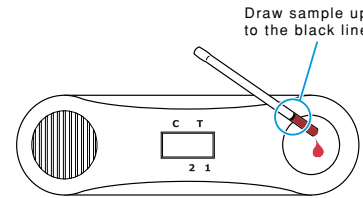


4. As the test begins to work, you will see purple color move across the Result Window in the center of the Test Device.



5. While results can often be seen within 2-3 minutes, interpret the test results at 7 to 8 minutes. Very weak samples may appear at 15 minutes. **Do not interpret test result after 20 minutes.**

FIGURE 1



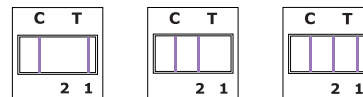
CAUTION: The above interpreting time is based on reading the test results at room temperature of 15 to 30 degrees C. If your room temperature is significantly lower than 15 degrees C, then the interpreting time should be properly increased.

INTERPRETATION OF THE TEST

1. A purple band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another purple band appears at the right section of the Result Window, this band is the Test Band.

POSITIVE RESULT: TWO/THREE PURPLE BANDS

FIGURE 2

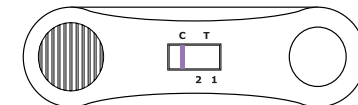


The presence of two or three purple bands (“T” band and “C” band) within the Result Window, no matter which band appears first, indicates that antibodies against HIV-1 and/or HIV-2 are detected (Figure 2). Note: Generally, the higher the antibody level in the specimen, the stronger the “T” band color will be. When the specimen antibody level is close to, but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

If the test band next to the number 1 appears, the patient probably has been infected by HIV-1. If the test band next to the 2 appears, the patient probably has been infected with HIV-2. In some cases both the HIV-1 and HIV-2 bands may appear indicating a dual infection with HIV-1 and HIV-2 or the presence of cross reacting antibodies to HIV.

NEGATIVE RESULT: ONE PURPLE BAND

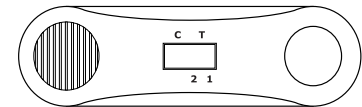
FIGURE 3



The presence of only one purple control line within the Result Window indicates that antibodies against HIV-1 or HIV-2 are not detected (Figure 3).

INVALID RESULT:

FIGURE 4



If after performing the test, no purple Control Line is visible within the Result Window, the result is considered invalid (Figure 4). Causes of invalid results are: improperly following directions or the test is beyond expiration date. It is recommended that the specimen be re-tested using a new test kit.

LIMITATIONS OF THE TEST

Although a positive result may indicate infection with HIV-1 and/or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds if an individual meets the case definition for AIDS established by the Centers for Disease Control. For samples repeatedly testing positive, more specific supplemental tests must be performed. A single immunochromatographic test alone cannot be used to diagnose AIDS, even if the antibodies against HIV-1 and/or HIV-2 are present in a patient specimen. A negative result at any time does not preclude the possibility of HIV-1 or HIV-2 infection.

PERFORMANCE CHARACTERISTICS

No standards for performance have yet been established for HIV rapid assays.

Results of testing from the National Aids Reference Lab (NARL), the WHO-recognized National Institute for Virology, in-house testing of the World-Wide BBI Performance panel comprising of all seven serotypes of HIV-1 (A-G), HIV-O, and HIV-2, as well as other panels, are as follows:

Test	Positives	Negatives	Sen%	Spec%
JN-QC™	81/183	09/115	98.9%	94.78%

While the number of samples tested was limited, the JN-QC™ HIV-TriLine rapid assay detected most positive samples used in these panels and was more sensitive than every other test.

REFERENCES

1. Gallo, RC et al. Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS. Science 1984; 224:500-503.
2. Clavel, F. et al. HIV-2, the West African AIDS Virus. AIDS 1987; 1:135-140.